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Customer Number

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: SHAFER, LISA L.
Application No.: 10/820,937 Group Art Unit: 3766
Filed: April 8, 2004 Examiner: Jessica L. Reidel
Title: DEVICE AND METHOD FOR INHIBITING RELEASE OF PRO-
INFLAMMATORY MEDIATOR

DECLARATION OF DR. LISA L. SHAFER UNDER 37 CFR §1.131

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

I, Lisa Lynn Shafer PhD, declare that:

1. I am a U.S. citizen and a resident of Stillwater, Minnesota.
2. I am employed by Medtronic, Inc. and I am the inventor of U.S. Patent Application Serial No. 10/820,937, filed April 8, 2004, and titled DEVICE AND METHOD FOR INHIBITING RELEASE OF PRO-INFLAMMATORY MEDIATOR, which application claims priority to provisional application No. 60/507,855, filed on October 1, 2003.
3. I have read and understood the Office Action for U.S. Patent Application Serial No. 10/820,937 mailed August 18, 2006.
4. I have attached technical notebook pages 8 and 9 from notebook number 10974 to provide evidence of conception of the claimed invention. The activity described in notebook

number 10974, pages 8 and 9 was carried out before June 9, 2003 in the United States of America.

5. I have attached a document entitled "FINAL REPORT" from Medtronic Physiological Research Laboratories to provide evidence of diligent reduction to practice of the claimed invention from prior to June 9, 2003 to October 1, 2003. Medtronic Physiological Research Laboratories was contracted to carry out studies presented in the FINAL REPORT under my direction.

a. Table 1 at page 14 of Appendix A of the FINAL REPORT outlines testing done on pigs and the dates such tests were performed. As can be seen in the report, pilot testing was performed on and before March 25, 2003 to establish a lipopolysaccharide (LPS) sepsis model in pigs. The porcine sepsis model served as a basis for testing whether stimulation of a sympathetic nerve, specifically the splenic nerve, could modulate an inflammatory immune response. The animals tested in the pilot studies received electrical stimulation of the splenic nerve and served as a vehicle for refining the surgical and stimulation procedures to be used in the larger scale study that followed.

b. Table 1 of Appendix A of the FINAL REPORT further shows that additional testing was performed after June 9, 2003. Specifically, on June 11, 2003, June 27, 2003, and July 3, 2003, pigs received LPS. On July 11, 2003, a pig to serve as a negative control for stimulation received LPS and its splenic nerve was cut. On July 29, 2003 the splenic nerve of a pig to serve as a negative control for LPS was stimulated. On September 9, 2003, a pig received LPS and stimulation. Inhibition of an inflammatory immune response by stimulation of a sympathetic nerve, namely the splenic nerve, was shown with the September 9, 2003 experiment.

c. Figure 7 of Appendix A of the FINAL REPORT is a graph of results obtained from, among other things, the June 9, June 11, June 27, July 3, July 11, July 29, and September 9, 2003 experiments. Figure 7 shows that splenic nerve stimulation in animal

Application No.: 10/680,693

Case No.: 58629US002

on September 9, 2009 prevented the reduction in white blood cell count that was observed in animals receiving LPS alone.

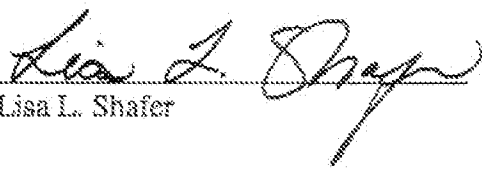
d. Figure 8 of Appendix A of the FINAL REPORT is a graph of results obtained from, among other things, the June 9, June 11, June 27, July 3, July 11, July 29, and September 9, 2003 experiments. Figure 8 shows that that splenic nerve stimulation in animal on September 9, 2009 prevented the increase in TNF alpha, IL-1m and IL-6 levels that were observed in observed in animals receiving LPS alone.

6. Provisional application Serial No. 60/507,855 was filed on October 1, 2003 and describes stimulation of the sympathetic nervous system, a nerve thereof or an end organ innervated thereby to inhibit an inflammatory immune response.

7. The present US application, application serial no. 10/820,937, was filed on April 8, 2004 and claims priority to provisional application serial no. 60/507,855

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 11/16/06

By: 
Lisa L. Shafer

Enclosures:

1. Technical notebook pages 8 and 9 from notebook number 10974
2. FINAL REPORT with Appendix I